UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

UNITED STATES OF AMERICA ex rel. John King and Jane Doe, et al.,	§	
Plaintiffs,	§	
vs.	§	CIVIL ACTION NO. 06-2662
SOLVAY S.A., et al.,	§	
Defendants.	§	

DEFENDANT SOLVAY PHARMACEUTICALS, INC.'S REPLY MEMORANDUM IN SUPPORT OF ITS RENEWED MOTION FOR PARTIAL SUMMARY JUDGMENT ON RELATORS' P&T-COMMITTEE-INFLUENCE THEORY

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INTRODUCTION

Relators' Opposition to SPI's motion for partial summary judgment on the P&T-committee-influence theory is most notable for what it does not say. First, the Opposition does not argue that P&T committees determine whether an off-label use of a drug is reimbursable as a "medically accepted indication." Nor does it argue that Preferred Drug Lists (PDLs) or for that matter any "administrative control" serves that function. And that is because none of them do. When it comes to the Medicaid claims for off-label uses Relators placed at issue, the Medicaid statute defines "medically accepted indication" and nowhere do Relators argue that any "administrative control" can or has expanded that definition. Second, the Opposition does not argue that SPI has misinterpreted any of the PDL evidence on which SPI's motion is based. As such, the Opposition does not raise a genuine issue of material fact as to whether SPI caused the submission of false claims through its interactions with members of P&T committees. That alone is grounds to grant the motion. See Gonzales v. AutoZoners, LLC, 860 F. Supp. 2d 333, 341 (S.D. Tex. 2012) (granting summary judgment motion where plaintiff "fails to dispute Defendants' evidence on this point").

Instead, Relators filed an Opposition laden with largely irrelevant and generally unsupported assertions and hundreds of "exhibits"—without explaining how—or if—anything in any of these exhibits creates a genuine dispute of fact. Many of these exhibits have nothing to do with P&T committees or PDLs, and Relators fail even to mention more than 100 exhibits in either the Opposition itself or its extensive "Appendices." The Opposition calls out, as though it supports Relators' theory, deposition testimony in which a former SPI employee explained her understanding that "dossiers" submitted to P&T committees are non-promotional and thus not subject to FDA's prohibition on off-label promotion. Opp. 3-4. "Dossier" is a term of art

meaning a non-promotional submission made to state Medicaid agencies, managed care plans, and compendia to evaluate a drug. The practice of submitting dossiers was—and still is—an unremarkable, generally-accepted industry practice of pharmaceutical and biotech manufacturers. Relators offer no legal support for their notion that this testimony was incorrect, nor do they identify any purported link between non-promotional dossiers and false claims.

At its core, the Opposition mischaracterizes the Court's prior rulings, the basis for SPI's motion, and Relators' own complaint. It insists that SPI and the Court should have guessed that Relators' allegations about improperly influencing P&T committees were about something else entirely because Relators meant to plead improper influence on all stripes of Medicaid decision makers with any involvement in "administrative controls" that can affect drug "utilization." Litigation, however, is not a game of whack-a-mole. Nothing in the Opposition defeats SPI's straightforward arguments for summary judgment on the theory Relators actually pled—that SPI caused claims for off-label uses of the three drugs by improperly influencing Medicaid P&T committees to obtain preferential listings on PDLs and Medicaid formularies.

ARGUMENT

A. PDLs cannot expand the universe of "medically accepted indications" reimbursed by a state Medicaid plan.

SPI detailed the inconsistency of Relators' P&T-committee-influence theory with the applicable statutory and regulatory framework governing Medicaid reimbursement. Dkt. 304, Motion for Partial Summary Judgment (MPSJ) 7-9, 24-26. This framework does not authorize P&T committees to expand the universe of off-label prescriptions reimbursed by Medicaid beyond the bounds of the "medically accepted indications" set by the Medicaid statute. Id. Pursuant to that statute, "medically accepted indications" are those included in a drug's FDA-approved label or those supported by references included in one of the compendia designated in

the Medicaid statute. Dkt. 153, Order at 8 n.10. P&T committees may choose to prefer one drug over another for the treatment of the drugs' medically accepted indications, and that preference may increase "utilization" when the drug is compared to non-preferred drugs in its class, but P&T committees do not do what Relators alleged—they do not have the authority to expand or contract the list of "medically accepted indications" of a drug that a state Medicaid plan can cover, and no amount of wooing, lawful or otherwise, can change their authority.[1] Relators' Opposition provides no substantive response to this argument raised in SPI's motion.

Instead, Relators argue only that the Court previously "rejected" the argument (Opp. 1, 5), ignoring that the Court invited SPI " 'to reassert its arguments at the summary judgment stage.' " Dkt. 173, Order at 9. Relators have now been afforded every opportunity to provide evidence to support their theory, and they have none because none exists. SPI asks the Court to rule that, based on the summary judgment record, Relators cannot show that a preferred listing on a PDL expanded the covered uses of Aceon, AndroGel, or Luvox. The statutory and regulatory framework that SPI laid out in its motion is unambiguous and remains wholly unrefuted: The uses of a drug that states' Medicaid programs cover are determined by the FDA-approved or compendia-supported indications, not by PDLs. MPSJ 7-9, 24-26.[2] SPI is thus entitled to summary judgment on Relators' P&T-committee-influence theory in its entirety.

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[1] Relators themselves describe their theory as improperly influencing P&T committees "to obtain coverage that would not otherwise have been available." Opp. 3 n.1 (emphasis added).

[2] Relators' reference to a press release and a complaint filed by the State of Texas in another matter does not create a genuine issue of material fact. Opp. 33-34. The press release (Opp. Ex. 83) merely describes a settlement agreement without any mention of false claims, the federal False Claims Act or any state counterpart. And the complaint (Opp. Ex. 68), like any complaint, consists of a series of allegations and theories of liability; it does not establish their merit, as demonstrated by the judgment entered in that case after the parties executed a settlement agreement: "Defendants deny all of the Plaintiffs' claims and allegations and deny they have any liability relating to such claims and allegations. This judgment does not constitute a finding that Defendants were liable for the claims asserted in the law suit." Agreed Final Judgment, Cause No. D-1-GV-04-001288, available from the Travis County records website, http://www.co.travis.tx.us/district_clerk/public_access.asp.

B. The Opposition does not dispute any of SPI's evidence about PDL listings.

SPI's motion also carefully detailed, on a state-by-state basis, the uncontroverted evidence about which states have used PDLs, when they did so, and whether SPI's drugs were listed as preferred on those PDLs. MPSJ 11-22. Relators' response is classic hand waving: without addressing—or disputing—the PDL evidence, Relators argue that they have another theory in which PDL evidence is not the main event. The Opposition makes no effort to demonstrate any material dispute of fact about what the PDL evidence shows as to when, where, and if SPI's drugs were listed as preferred; Relators have essentially conceded SPI's motion as it relates to PDL listings themselves. Thus, and in the alternative, SPI is entitled to summary judgment on Relators' P&T-committee-influence theory (1) as to all of the states and drugs for which Relators "no longer assert" the theory, (2) as to all of the states that had not implemented a PDL during the Relevant Time, (3) to the extent that each state's PDL did not list Aceon, AndroGel, or Luvox as preferred, and (4) where there is no evidence that SPI's drugs were listed as preferred on a state's PDL during the relevant time period. MPSJ 26-29.[3]

C. Relators' "formulary" argument is based on an unreasonable inference.

SPI's motion explained that the P&T-committee-influence theory also fails to the extent it is based on Medicaid formularies because no state has implemented a Medicaid formulary. MPSJ 30-31. Relators agree that no state has "technically" implemented a Medicaid formulary. Opp. 7. Instead, they argue that because some SPI employees used the phrase "on formulary" in internal emails or planning documents, the Court should infer that the Fifth Amended Complaint (5AC) allegations about improperly obtained placement on Medicaid "formularies" meant

[3] SPI's efforts to review and analyze Relators' brief, appendices, and nearly 400 exhibits revealed only one minor scriveners' error in the summary chart of the PDL evidence (MPSJ Ex. 8) and the corresponding description of that chart at MPSJ 11-12, 27-28. In Tennessee, AndroGel was listed as preferred from August 1-December 1, 2007. See MPSJ Exs. 464-66.

whatever Relators now claim the phrase meant in those documents. Id. There is no basis for such an indulgence.

In Paragraphs 39-40 of the 5AC, Relators explained the requirements for a Medicaid formulary, citing the very same statutory provisions that SPI relied on in its summary judgment motion. The 5AC then alleged that SPI improperly sought to "obtain placement of its drugs on the state Medicaid formularies." 5AC ¶ 287. The only reasonable inference is that the Medicaid formularies Relators were referring to in paragraph 587 were the same Medicaid formularies they had earlier described in paragraphs 39-40. Any other inference would be unreasonable. See, e.g., Millennium Mkg. Gp., LLC v. United States, 2008 WL 4461999, at *5 (S.D. Tex. Sept. 29, 2008) ("unreasonable inferences are insufficient to meet the burden of establishing a genuine issue of material fact"). As a result, summary judgment is warranted on Relators' theory as it relates to Medicaid formularies because the evidence is undisputed that no state has implemented one.[4]

D. Relators mischaracterize SPI's argument about the role of PDLs and the operative allegations in the Fifth Amended Complaint.

Relators criticize SPI for arguing that PDLs "are the sole way to determine a state's reimbursement of a drug." Opp. 9. SPI made no such argument. SPI's motion focused on P&T committees and the PDLs they authorize because that is what Relators alleged was at issue in the 5AC. 5AC ¶¶ 287-95; see also Dkt. 153, Order at 10, 27, 31, 40, 62-64. The 5AC did not allege improper wooing of DUR Boards or improperly gained exclusions from other types of prior authorization or administrative controls. MPSJ 31-32; see generally 5AC.

[4] Because many private insurance companies use formularies, including some that manage Medicaid managed care programs, it is unsurprising that some SPI employees would refer to drugs being "on formulary" without meaning a Medicaid formulary as described in 5AC ¶¶ 39-40. State P&T committees play no role in establishing formularies for private insurance companies, which have their own P&T committees.

The Opposition's assertion (at 7) that "Relators' claims were always about SPI's efforts to influence decision makers of all types, including DUR Board members, to obtain preferential reimbursement status throughout the relevant period," is belied by the very paragraphs of the 5AC they cite: ¶¶ 287-298. That section of the 5AC is entitled "Wooing Medicaid P&T Committee members" (emphasis added) and all of its allegations refer to P&T committees, P&T committee members, and P&T committee meetings. No DUR Board or other "decision maker" is mentioned. Relators admit not mentioning DUR Boards before they unilaterally amended the background section of the 5AC (¶¶ 39, 41), but ignore that they previously told the Court that the 5AC did not change their allegations about wooing P&T committee members which had been "comprehensively alleged in the Fourth Amended Complaint" and was "unchanged" in the 5AC. Dkt. 163 at 14-15. Relators cannot now call a mulligan and change their mind.[5] Not only did the 5AC make no allegation about SPI's dealings with DUR Boards, but the Opposition itself acknowledges (at 13) that DUR Boards "function independently" of P&T committees. Moreover, Relators make no effort to show that DUR Boards affect the "medically accepted" indications that the Medicaid statute requires be covered. Simply put, Relators' newfound arguments about DUR Boards have no relevance to the 5AC's allegations.

Relators' arguments about "administrative controls" and non-PDL "preferential reimbursement status" (e.g., Opp. 1, 7, 9, 12) are also irrelevant to those allegations. Neither term appeared in the 4AC or the 5AC; nor did either complaint describe the allegations about PDLs and Medicaid formularies as part of some broad category of administrative controls. The Court should reject Relators' efforts to inject any of these concepts into the case once and for all.

[5] Moreover, Relators' leave to file a 5AC extended only to re-pleading the claims that had been dismissed without prejudice, not expanding to or adding new ones. Dkt. 153 at 131 (leave to re-plead "only those claims" that were dismissed without prejudice (emphasis in original)).

E. The Court need not consider Relators' "evidence."

The purported "evidence" submitted with the Opposition does not help Relators avoid summary judgment. For one thing, the Opposition never even references some 230 of the 379 "exhibits" Relators filed with it.[6] For another thing, many of the exhibits (cited and not cited) relate to things other than P&T committees and PDLs. In addition, for a substantial number of exhibits, Relators do not attempt to establish that this purported "evidence" is admissible or for what purpose. Many are internal SPI documents, but those documents contain hearsay to the extent Relators offer them as evidence of a state Medicaid program's coverage decisions. See, e.g., Opp. Ex. 183, 184, 249, 272, 290. As discussed above, the Opposition does not dispute any of SPI's evidence about PDL lists, and exhibits used in support of Relators' arguments about DUR Boards, "administrative controls," and non-PDL "preferential reimbursement status" are irrelevant to the allegations of the 5AC.

SPI has scoured Relators' brief and appendices for arguments or evidence related to PDL listings of its drugs. Relators do not contend to have identified preferred PDL listings beyond those SPI submitted. Cf. Skotak v. Tenneco Resins, Inc., 953 F.2d 909, 915–16 & n.7 (5th Cir. 1992) (it is not the court's responsibility "to sift through the record in search of evidence to support a party's opposition to summary judgment."). Instead, they often mischaracterize those few exhibits that do touch on PDLs in some way. For instance, Relators repeatedly assert that a state "implemented" a PDL in a given year by citing a list of PDL-related legislation compiled by the National Conference of State Legislatures. E.g., Opp. 14, 33 (citing Opp. Ex. 288). That

[6] About half of these 230 exhibits were referenced in 41 pages of additional briefing Relators' styled "appendices" and filed without leave of Court. See Opp. Appx. B, C, and D (Dtk. 351-6, 351-7, 351-8). As SPI informed Relators' counsel it would at the time they sought consent for leave to file a 35-page Opposition, SPI objects to the filing of the Appendices and the Exhibits cited only therein. The Appendices are a far cry from the sort of summary exhibit that is admissible under Fed. R. Evid. 1006, and the documents they purport to summarize often do not support the arguments their Appendices assert.

list shows when certain legislation it characterizes as PDL-authorizing legislation was enacted, but SPI's evidence of actual PDLs shows that it often took months or years for a state to publish its first PDL.[7] As another example, Relators cite SPI's MPSJ Exs. 67-82 in stating AndroGel was granted preferred status "in September 2003, and AndroGel retained that status through at least 2007." Opp. Appx. D at 3. But SPI submitted PDLs from Florida dated Nov. 9, 2005, Feb. 3, 2006, and Feb. 21, 2006 on which AndroGel was not preferred and required prior authorization. MPSJ Exs. 8, 85M-O.

The only other "evidence" cited in the Opposition is a single deposition question and answer. Opp. 3-4. In the quoted text, the former SPI employee explained—correctly—that manufacturers provide non-promotional submissions, called "dossiers," to state and private P&T committees, compendia, and others to help them evaluate a drug and that dossiers include information about off-label uses that is generated through a literature search, much like a compendia listing. Opp. Ex. 234. It is not clear how Relators think this testimony supports their case, but they seem to imply that these dossiers constitute off-label promotion. If that is what Relators are saying, it is more of a reflection of their misunderstanding about the confines of "off-label promotion" than anything else. Because physicians lawfully write prescriptions for off-label uses of drugs and insurers lawfully reimburse those claims, P&T committees have an obvious interest in assessing drugs in light of the full range of medically supported uses. For state P&T committees, that means evaluating all uses that meet the statute's definition of "medically accepted indications." See Dkt. 153, Order at 55.

"Dossiers"—industry shorthand for the package of materials submitted to managed care

[7] Compare, e.g., Opp. Ex. 288 at Kpro-00109293 (listing Colorado PDL-authorizing law in 2006 and 2007) with, e.g., MPSJ Ex. 640 at 6, Colorado PDL Program Annual Report, Jan. 1, 2008 – Dec. 31, 2008 (indicating Colorado's first PDL was effective Feb. 1, 2008).

plans for review—have long followed a format, according to the Academy of Managed Care Pharmacy (AMCP) that enables manufacturers to submit "information regarding off-label uses of the product" while staying "within regulatory constraints mandated by the Food and Drug Administration." [8] Nothing about such non-promotional dossiers supports Relators' theory that off-label communications with P&T committees caused any state Medicaid program to make reimbursable claims for otherwise non-reimbursable, off-label uses of drugs.

CONCLUSION

SPI respectfully requests that the Court grant its motion for partial summary judgment on Relators' P&T-committee-influence theory as to all remaining federal and state causes of action.

Dated: November 3, 2014

Respectfully submitted,

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[8] Academy of Managed Care Pharmacy (AMCP), Format for Formulary Submissions: A Format for Submission of Clinical and Economic Data in Support of Formulary Consideration by Managed Care Health Systems in the United States, at 1 (Oct. 2000), available at http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=16275.

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CERTIFICATE OF SERVICE

On the 3rd day of November 2014, a copy of Defendant Solvay Pharmaceuticals, Inc.s, Reply Memorandum In Support Of Its Renewed Motion For Partial Summary Judgment On Relators' P&T-Committee-Influence Theory was filed electronically using the Court's Electronic Case Filing System. Notice of this filing will be sent electronically to counsel of record using the Court's electronic notification system. Parties may access this filing through the Court's Electronic Case Filing System.

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